

Approval of clinical trial application for NEX-22 study delayed

Nanexa AB today announces that in the ongoing review process of the clinical trial application for the phase I study with NEX-22, additional supplements have been requested from the German Medicines Agency, which in the new European regulatory process takes more time than expected.

Nanexa is developing NEX-22, a one-month product of the GLP-1 substance liraglutide, for the treatment of type 2 diabetes. In December 2023, the company submitted a clinical trial application for a first phase I study with NEX-22 and was informed during the first quarter of 2024 that certain supplements and clarifications of the application were requested, and most of these clarifications were also accepted by the authority during the first quarter. A few remaining supplements were handled quickly by Nanexa, but with the new European system for reviewing clinical trials, a new submission of the application was required, which in itself has delayed the process. Nanexa has now received some additional questions from the authority based on the new review of the application. The company sees no difficulty in answering these, but the application will not be approved in April with the current timeline.

"We aimed to start the study in the first quarter and are of course disappointed that the approval process is taking longer than expected. Both the need to resubmit the application and the fact that new questions have been added are causing delays. However, we feel confident that we can handle all issues and our current assessment is that we can obtain approval and start the study towards the end of the second quarter. With this schedule, we will still be able to obtain important clinical data before the end of the year. Otherwise, we are as ready as we can be, the clinical trial material is manufactured and our clinic is ready to recruit patients as soon as we have an approval", says David Westberg, CEO of Nanexa.

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The company's Certified Adviser is Carnegie Investment Bank AB (publ).

About Nanexa AB (publ)

Nanexa is a pharmaceutical company developing injectable drug products based on the proprietary and innovative drug delivery system PharmaShell® – the high drug load delivery system enabling the next generation long-acting injectables through atomic layer precision. Nanexa develops its own products and also has collaboration agreements with several pharma companies, among others Novo Nordisk and AstraZeneca.

Nanexa's share is listed on Nasdaq First North Growth Market in Stockholm (NANEXA).

Attachments

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